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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/038,108

10/19/2001

John L. Baker

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5379

7590

01/27/2003

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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 01/27/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/038,108

Applicant(s)

BAKER, JOHN L.

Examiner

David H Kruse

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1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR § 1.78(a)(2) and (a)(5)). The following wording is suggested, -- This application is a continuation of U.S. Patent application 09/319,197, filed 28 July, 1999, now abandoned, which is the national stage application of PCT/US97/22259, filed 2 December, 1997, which claims priority to U.S. Provisional Application 60/032,303, filed 2 December 1996. --

### ***Information Disclosure Statement***

2. The information disclosure statement filed 19 October 2001 has been considered, a signed copy is attached hereto.

### ***Oath/Declaration***

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR § 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: PCT/US97/22259 was not filed within 12 months of the filing of U.S. Patent application 09/319,197 and thus Applicant cannot claim priority under 35 U.S.C. § 119 (a)-(d) to said PCT application. Parent Application 09/319,197 was filed as the National Stage Application under 35 U.S.C. §

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371, this information should be clearly stated on the Declaration. See 37 CFR § 1.63

(d)(1)(i).

### ***Claim Objections***

4. Claims 8 and 14 are objected to because of the following informalities: Said claims lack an article of language and should read -- A tissue culture --. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-16 are rejected because at claim 1, the sole designation of a plant by its breeding line name or number is arbitrary and creates ambiguity in the claims. For example, the plant disclosed in this application could be designated by some other arbitrary means, or the assignment of the breeding line name could be arbitrarily changed to designate another plant. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to the deposit accession number of the claimed breeding line would obviate this rejection.

At claim 1, line 2, the parenthetical limitation "(to be assigned)" renders the claim indefinite because it is unclear what the metes and bounds of this limitation are.

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At claims 7 and 11, the limitation "sowing" is indefinite because one of skill in the art would not use the term "sowing" in relation to a "reproductive root from the plant".

Amending said limitation to read -- planting -- would obviate this rejection.

At claim 14, the phrase "or its progeny" is indefinite because it is unclear if this phrase refers to the "seed" or the "plant".

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-16 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a *Boehmeria nivea* plant, seed and parts thereof, a method of propagating said plant, and an animal feed comprising said plant designated P.I. 87521-X.

Applicant describes a plant having the phenotype of a *Boehmeria nivea* plant designated P.I. 87521-X (see the entire specification).

Applicant does not describe a reproducible method of making said *Boehmeria nivea* plant designated P.I. 87521-X.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed. See MPEP § 2406.01 for guidance.

The statement filed 3 June 2002 under 37 CFR § 1.809(b)(1) is noted, but this

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statement does not obviate the need for an adequate written description in the specification of the claimed invention.

9. Claim 13 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The issue of indefiniteness is discussed supra.

Applicant claims a progeny of a *Boehmeria nivea* plant designated P.I. 87521-X or a progeny of a seed of said plant.

Applicant describes a *Boehmeria nivea* plant designated P.I. 87521-X.

Applicant does not describe progeny of a *Boehmeria nivea* plant designated P.I. 87521-X.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed

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genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Applicant does not describe any unique feature of said *Boehmeria nivea* plant that would distinguish it's progeny from say the *Boehmeria nivea* plant designated PI 87521 (see Dudienas *et al* 1984 (Fitopathologia Brasileira 9:551-554)). Once the described *Boehmeria nivea* plant designated P.I. 87521-X is crossed with another plant it is unclear from the instant specification that any unique feature of said plant would be passed on in progeny of the *Boehmeria nivea* plant designated P.I. 87521-X due to crossing over at random loci and segregation. Hence, it is unclear that Applicant can adequately describe a progeny plant produced from the *Boehmeria nivea* plant designated P.I. 87521-X as claimed.

10. Claims 1-16 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily

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available to the public. It is noted that applicants intend to deposited the plant under the criteria set forth in 37 C.F.R. §§ 1.801-1.809, see the Statement filed 6 June 2002 under 37 CFR § 1.809(b)(1).

In addition, Applicant must amend the instant specification to denote that a deposit has been made, with what depository the deposit was made, when the deposit was made, and what the Accession Number of the deposit is. See the rejection for written description above for guidance.

11. Claim 13 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The issue of indefiniteness is discussed supra.

Applicant claims a progeny of a *Boehmeria nivea* plant designated P.I. 87521-X or a progeny of a seed of said plant.

Applicant teaches a *Boehmeria nivea* plant designated P.I. 87521-X.

Applicant does not teach progeny of a *Boehmeria nivea* plant designated P.I. 87521-X.

*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art,



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the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant provides limited guidance on how to make and use progeny plant of the *Boehmeria nivea* plant designated P.I. 87521-X. The claims are broadly drawn to any progeny plant of an undesignated number of generations away from the *Boehmeria nivea* plant designated P.I. 87521-X. The nature of the invention is such that one of skill in the art would recognize that transferring a unique trait based only on phenotypic characteristics is unpredictable without extensive guidance.

Hunsperger et al (1996, U.S. Patent 5,523,520), Kraft et al (2000, Theor. Appl. Genet. 101:323-326), and Eshed et al (1996, Genetics 143:1807-1817) teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (see, e.g., column 3, lines 26-46). In particular, Hunsperger et al teach that a gene conferring miniature plant stature which has been identified and genetically stabilized in one cultivar of *Petunia hybrida*, a member of the Solanaceae, does not confer a miniature phenotype when introgressed into the genome of a variety of other *Petunia hybrida* cultivars (see, e.g., column 3, lines 40-41).

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Kraft et al teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype- specific and loci-dependent in nature (see, e.g., page 323). Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is typically known about the plant breeding materials, which contributes to the unpredictability of the effect. Eshed et al teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (see, e.g., page 1815).

Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to predictably make and use a progeny plant of the *Boehmeria nivea* plant designated P.I. 87521-X, in particular to reliably and predictably transfer the trait of freeze and frost-resistance as taught in the specification.

***Claim Rejections - 35 USC § 102/103***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 9 and 15 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Dudienas *et al* 1984 (Fitopathologia Brasileira 9:551-554).

Dudienas discloses a *Boehmeria nivea* plant designated PI 87521 (see the Abstract on page 551).

Dudienas does not teach a *Boehmeria nivea* plant designated PI 87521-X.

The regenerated plant of claims 9 and 15 would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention because there is no indication in the specification or the claims that such a regenerated plant would necessarily have all of the morphological and physiological characteristics of a *Boehmeria nivea* plant designated PI 87521-X. Given somoclonal variation of plants regenerated from tissue culture, it is unclear from the instant specification, how stable the unique characteristics of the *Boehmeria nivea* plant designated PI 87521-X are.

15. Claim 13 is rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Dudienas *et al* 1984 (Fitopathologia Brasileira 9:551-554).

Dudienas discloses a *Boehmeria nivea* plant designated PI 87521 (see the Abstract on page 551).

Dudienas does not teach a *Boehmeria nivea* plant designated PI 87521-X.

A progeny plant of the *Boehmeria nivea* plant designated PI 87521-X, produced after an undesignated number of generations would be *prima facie* indistinguishable

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from a progeny *Boehmeria nivea* of the plant designated PI 87521 as disclosed or taught by Dudienas.

16. Claims 10 and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Machin 1977 (Tropical Science 19(4):187-195) in view of Dudienas *et al* 1984 (Fitopathologia Brasileira 9:551-554) and Applicant's admission.

Machin teaches the use of ramie, *Boehmeria nivea* (L.) Gaudich as an animal feed (see the Abstract on page 187).

Machin does not teach an animal feed comprising a *Boehmeria nivea* plant designated PI 87521-X.

Dudienas teaches a *Boehmeria nivea* plant designated PI 87521.

Applicant admits that the claimed *Boehmeria nivea* plant designated PI 87521-X as developed from a *Boehmeria nivea* plant designated PI 87521 (see page 7 of the specification).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to use the *Boehmeria nivea* plant designated PI 87521 of Dudienas to make an animal feed as taught by Machin. Applicant admits that the claimed *Boehmeria nivea* plant was developed from a known plant variety, and that Applicant's own comparisons in Table 3 on pages 8-9, show that any characteristic that could be used to distinguish an animal feed made by either plant is identical in both PI 87521 and PI 87521-X.

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**Conclusion**

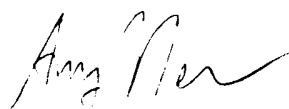
17. Claims 1-8, 11, 12 and 14 are free of the prior art which neither teaches nor fairly suggests a *Boehmeria nivea* plant designated P.I. 87521-X or method of using same.

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



AMY J. NELSON, Ph.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1000

David H. Kruse, Ph.D.  
21 January 2003